DEC - 2 2011

EXHIBIT 02

K112559

**PREMARKET NOTIFICATION 510(k) SUMMARY**
**As required by 21 CFR §807.92(c)**

## Submitter

| | |
|---|---|
| 510(k) Owner: | MedApps, Inc. |
| Owner / Operator: | 10027842 |
| Registration: | 3005916763 |
| Address: | 7975 North Hayden Road, Suite A-203, Scottsdale, AZ 85258 |
| Telephone: | 480-305-6323 |
| Fax Number: | 480-393-1892 |
| Contact Person: | Kent Dicks |
| Contact Person Title: | Founder / CEO |
| Date Prepared: | August 31, 2011 |

## Device Information

| | |
|---|---|
| Trade Name: | MedApps 2.0 - Remote Patient Monitoring System |
| Common Name: | Remote Patient Monitoring System |
| Classification Status: | Class II per regulations 870.2910 |
| Classification Name: | Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG) |

## A. LEGALLY MARKETED PREDICATE DEVICE

Legally marketed predicate devices are:

| | |
|---|---|
| K080798 | Intel Health Guide PHS6000 |
| K072698 | Confidant 2.5 |
| K062377 | MedApps Remote Patient Monitoring System (D-PAL) |
| K083862 | MedApps 2.0 - Remote Patient Monitoring System |

## B. INDICATIONS FOR USE

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, a mobile over-the-counter wireless communication hub, or MedApps HealthAIR, a portable over-the-counter wireless communication hub, which connects to commercially available glucose meters, scales, blood pressure monitors and pulse oximeters and HealthCOM, MedApps' secure host server system.

MedApps Remote Patient Monitoring devices receive and store measurements collected from the described monitors, either wirelessly (HealthPAL) or tethered (HealthPAL or HealthAIR). MedApps devices do not alter the indicated use of the peripheral monitors that they integrate with. MedApps devices indicate successful or failed reception and transmission of data with visual and audio cues (HealthPAL via OLED display screen, verbal message and audio tones; HealthAIR via LED lights and audio tones). MedApps devices store collected data and transmit to

HealthCOM using commercially available, FCC compliant, wireless telecommunication protocols (including but not limited to cellular GSM, CDMA and WiMax).

Healthcare professionals can review the transmitted information within the MedApps HealthCOM system, set thresholds to flag readings based on specific thresholds being exceeded. In addition, the MedApps Interactive Voice Response (IVR) has the ability to contact the patient remotely and use pre-approved ("canned") educational or reminder messages. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

The MedApps 2.0 - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

## C. MedApps 2.0 SYSTEM DESCRITPION

The MedApps 2.0 - Remote Patient Monitoring System consists of:

(1) MedApps HealthPAL hardware:

The physical component of the MedApps HealthPAL is an electronic device contained in a plastic enclosure with an OLED screen, built-in M2M cellular chip, speaker, smart cable connection, smart cables, wireless module, LED lights to indicate activity, timer button to assist patients with their reading schedule (i.e. remind them to take their reading in X minutes), last reading button, volume up and down buttons.

(2) MedApps HealthPAL firmware / software:

The firmware captures data from commercially available health monitors, and stores and transmits the information to the MedApps HealthCOM server, via the embedded communication chip / platform.

The firmware allows HealthPAL to receive information via wire or via embedded wireless module from accessory medical devices that are compatibly wireless enabled, which have been paired to the MedApps HealthPAL.

The firmware has many additional functions including:

- Download of user profiles from the server to configure HealthPAL remotely.

- HealthPAL has audio capability to deliver verbal announcement of readings and acknowledgment of data transmission from all connected accessory medical devices, time settings, volume control, educational content and reminders, in any language that is loaded to the device.

- Timer capability, activated by the user to provide assistance with adhering to a reading schedule (reminders to take readings within a set timeframe).

- OLED screen displays information regarding the HealthPAL's status including battery level, volume level, data transmission status, transmission pending indicator, activity icons / messages and other information to provide ease of use and promote patient adherence; as well as information received from accessory medical devices, such as the type of device, measurement, date and time of the last reading collected.

- Battery charging, isolation circuits, and interfaces to individual accessory medical devices / protocols via the smart cable.

(3) MedApps HealthAIR hardware / software:

MA020 HealthAIR is a modified MA105 HealthPAL device. The physical component of the MedApps HealthAIR is an electronic device contained in a plastic enclosure with built-in M2M cellular chip, speaker, standard USB cable and USB Smart Cable connection, and LED lights to indicate activity regarding the receiving and transmitting of collected data.

Like the HealthPAL, HealthAIR's firmware / software captures, data from commercially available retail health monitors, and stores and transmits information to the MedApps HealthCOM server, via the embedded communication chip / platform.

The firmware allows HealthAIR to receive information via wire, either standard USB or with a MedApps USB Smart Cable, from accessory medical devices.

The firmware has many additional functions including:

- Download of user profiles from the server to configure HealthAIR remotely.

- HealthAIR's Audio feature uses audio tones to indicate acknowledgment of collected readings from all connected accessory medical devices as well as reading transmission via the cellular network.

- HealthAIR's visual user interface utilizes LED lights of collected readings from all attached medical devices as well as reading transmission acknowledgements (via).

(5) MedApps HealthCOM software application:

The HealthCOM software application allows caregivers access to review patient data collected from accessory medical devices using MedApps hardware on the secure HealthCOM website. HealthCOM software allows professional caregivers to set patient readings.

HealthCOM software also allows the patient to establish an account and to direct / authorize their data to be directed to an outside, validated Personal Health Record (PHR), Electronic Health Record or Medical Record (EHR or EMR).

(6) MedApps IVR software application:

The IVR (Interactive Voice Response) software application provides the ability to contact the patient remotely, by phone (designated in the user profile), and executes an pre-approved ("canned") scripts to deliver pre-approved ("canned") reminder messages ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings"), educational content and gather survey information.

In addition, the MedApps IVR application will send out Email, SMS / Text Messages, Paging, IM and other forms of communications in order to contact patients or caregivers. This will include reminders and alerts, based on clinically defined parameters / thresholds established in HealthCOM by the professional care provider.

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## D. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

| **Feature** | **Intel Health Guide PHS6000**<br>**K080798** | **Confidant 2.5**<br>**K072698** | **MedApps Submission** ***(HealthPAL & HealthCOM)***<br>**K083862** | **MedApps Submission** ***(HealthAIR & HealthCOM)***<br>**K112559** |
|---|---|---|---|---|
| **Indications of Use** | Enables healthcare providers to monitor and manage chronic conditions of patients remotely | Same | Same | Same |
| **Intended Use** | Telemedicine System | Same | Same | Same |
| **Intended Users** | Home users and Healthcare providers | Same | Same | Same |
| **Site of Use** | Home, Clinic | Same | Same | Same |
| **Data Collection Software** | Intel Care Management Suite Software | The Hermes Proprietary Software | MedApps Proprietary Software | MedApps Proprietary Software |
| **Data Collection Software Functionality** | Transmit data from Sensor devices to Central Database | Same | Same | Same |
| **Communication method of hub with Central Server** | Via DSL or Phone Line Connection | Via Cellular Phone | Via Embedded Cellular Technology | Via Embedded Cellular Technology |

| Feature | Intel Health Guide PHS6000<br>K080798 | Confidant 2.5<br>K072698 | MedApps Submission *(HealthPAL & HealthCOM)*<br>K083862 | MedApps Submission *(HealthAIR & HealthCOM)*<br>K112559 |
|---|---|---|---|---|
| **Types of sensors which can be interfaced (wired or wirelessly) to receiver hub** | Medical Devices designed for Home use:<br>Glucose<br>Scale<br>Blood Pressure<br>Pulse Ox<br>Peak Flow | Medical Devices designed for Home use:<br>Glucose<br>Scale<br>Blood Pressure | Medical Devices designed for Home use:<br>Glucose<br>Scale<br>Blood Pressure<br>Pulse Ox | Medical Devices designed for Home use:<br>Glucose<br>Scale<br>Blood Pressure<br>Pulse Ox |
| **Implementation method of collecting data from sensors** | Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables. | Short range radio system using Bluetooth | Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables. | Currently using Wired (tethered) cables (USB), Smart Cables. |
| **Sensor Software** | Sensor Software unchanged | Same | Same | Same |
| **Connectivity** | Short range radio system using Bluetooth and Wired (tethered) cables. | Short range radio system using Bluetooth | Short range radio system using Bluetooth and Wired (tethered) cables. | Currently using Wired (tethered) cables<br>Future capability to use Bluetooth dongles. |
| **Communication method of hub with devices** | Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables. | Short range radio system using Wireless (Bluetooth) | Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables. | Currently using Wired (tethered) cables. |
| **Communications Protocol** | Wireless (Bluetooth) V2.0 & Wired (Tethered) | Wireless (Bluetooth) V2.0 | Wireless (Bluetooth) V2.0 and Wired (Tethered) | Wired (Tethered) |
| **Communication Frequency** | Bluetooth : 2.402 to 2.480 GHz | Bluetooth : 2.402 to 2.480 GHz<br>GSM: 850/ 900 / 1800 / 1950 Mhz | Bluetooth : 2.402 to 2.480 GHz<br>GSM: 850 / 900 / 1800 / 1950 Mhz | GSM: 850 / 900 / 1800 / 1950 |
| **Power Source** | Wall power plug (120 VAC/50-60) | Wall power plug (120 VAC/50-60) and Rechargeable Batteries in Device | Wall power plug (120 VAC/50-60) or Rechargeable Batteries in HealthPAL | Wall power plug (120 VAC/50-60) |
| **Visual Feedback / Display** | On devices and hub, and monitors connected to central server | Same | OLED for HealthPAL | HealthAIR uses LED light indicators |
| **Communication with Patients** | On screen display | Same | Audio/visual reading feedback on screen and by speaker; and Interactive Voice Response (IVR) System for patient contact | Audio/visual reading feedback from LED light indicators & audio tones; Interactive Voice Response (IVR) system for patient contact |

**Data Collection:**
The 2 predicate devices and the MedApps solution connect to medical devices (designed for home use) by either wired (cable) connection or wireless (HealthPAL- Bluetooth). The data is collected from the devices and sent to a secure central server using various communication methods.

**Telecommunication Platform to Central Server:**
Intel Health uses DSL connectivity (wired point of care), Confidant uses an off-the-shelf Cellular Phone; MedApps uses embedded Machine to Machine (M2M) module to transmit data via cellular connectivity.

**Patient Feedback Technology:**
The 2 predicate devices and the MedApps solution allow data and messages to be displayed on a screen (for the HealthPAL) for the patient to read and acknowledge. HealthAIR uses audio and visual acknowledgement / feedback. The MedApps solution also uses an Interactive Voice Response (IVR) system in order to call the patient and ask questions, gather survey information, or issue reminders.

**Backend Data Storage:**
All systems (both 2 predicate devices and the MedApps solution), provide a backend system that allows data to be stored, and healthcare professionals to access and monitor collected patient data.

## E. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW – as required by 807.92(b)(1)

**Non-Clinical Testing**
The submitted 2.0 System has undergone MedApps' design control verification and validation testing. MedApps 2.0 validation testing include testing of all executable code and functionality and confirmation that all identified risks have been adequately addressed by software functionality, the user interface, documentation or user SOP.

MedApps 2.0 System verification and validation activities as part of the design control process include testing of all Design Specifications (Design Control Inputs) based on risk analysis, certification standards, and Verification plans. MedApps Product Verification and Release Plan execution on both HealthPAL and HealthAIR ensures both medical devices work with each type of user accessory medical device (glucose, blood pressure monitor, scale, and pulse oximeter) as part of the MedApps 2.0 System including integration to HealthCOM backend software application. The output of these design control verification analysis documents **MedApps 2.0 - Remote Patient Monitoring System** shall meet its requirements and design specifications as intended.

Lastly, MedApps has used its Risk Management Plan to perform risk analysis comparing the current MA105 HealthPAL device to the modified MA020 HealthAIR device regarding residual risks, control analysis risks, and human management factors for usability to determine that no significant risks were added by allowing either the MA105 HealthPAL or the MA020 HealthAIR to be functionally used as part of the MedApps 2.0 System.

Lastly, all relevant certification testing such as EMC (60601-1-2) and Safety (60601-1) are described in MedApps' Declaration of Conformity.

## F. SUBSTANTIAL EQUIVALENT

The MedApps 2.0 Remote Patient Monitoring System is substantially equivalent to the predicate devices in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be integrated to the patient medical device, implementation methods of collecting data from sensors, sensor software, connectivity, communication protocol, power source and general display method.

The HealthAIR communication hub device is substantially equivalent to the HealthPAL (described in 510k K083862) as both devices, as part of the MedApps 2.0 System, connect to commercially available Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters; data is collected, stored and transmitted using off-the-shelf FCC approved wireless / cellular connectivity. Both provide audio and visual feedback / acknowledgement that readings have been collected and transmitted to MedApps' secure host server called "HealthCOM".

Below is a Technological Characteristics Summary between the HealthPAL and the HealthAIR medical devices:

| **Feature** | **MA105 HealthPAL** | **MA020 HealthAIR** |
|---|---|---|
| **Indications of Use** | Enables healthcare providers to monitor and manage biometirc patient data collected remotely | Same |
| **Intended Use** | Telemedicine System | Same |
| **Intended Users** | Home users and patients outside of the clinical setting, as well as Healthcare providers | Same |
| **Site of Use** | Remote setting (e.g. Home / Work), Clinic | Same |
| **Data Collection Software & firmware** | MedApps Proprietary Software | Same |
| **Data Collection Software Functionality** | Transmit data from Sensor devices to Central Database | Same |
| **Communication method of device hub with Central Server** | Via Embedded Cellular Technology (GSM or CDMA) | Same |
| **Types of sensors which can be interfaced (wired or wirelessly) to receiver hub** | Medical Devices designed for Home use:<br>Glucose, Scale, Blood Pressure Pulse Ox | Same |
| **Transmission** | Transmits information to the MedApps secure host server called "HealthCOM" | Same |
| **Implementation method of collecting data from sensors and general Connectivity** | Short range radio system using Wireless (Bluetooth) and Wired / tethered (Smart Cables). | HealthAIR uses wired / tethered connection (USB, Smart Cables) |

| | | |
|---|---|---|
| **Communication method of hub with devices** | Short range radio system using Wireless (Bluetooth) and Wired / tethered (Smart Cables). | HealthAIR uses wired / tethered connection (USB, Smart Cables) |
| **Communication Frequency** | Bluetooth : 2.402 to 2.480 GHz<br>GSM: 850 / 900 / 1800 / 1950 Mhz | GSM: 850 / 900 / 1800 / 1950 Mhz |
| **Power Source** | Wall power plug (120 VAC/50-60) and Rechargeable Batteries in Device | Same Wall power plug but HealthAIR does not have a rechargeable battery |
| **Device Communication with Patients** | On screen display and audio voice feedback | LEDs lights for visual feedback and audio tones (beeps). |
| **Certification Testing** | Safety 60601-1, EMC/EMI/FCC (60601-1-2), ESD & Radiated Immunity, FCC Bluetooth, (PTCRB), CTIA (battery), ETSI | Safety 60601-1, EMC/EMI/FCC (60601-1-2), ESD & Radiated Immunity, (PTCRB), ETSI *(See Declaration of Conformity)* |

## G. SAFETY AND EFFICACY

The MedApps 2.0 Remote Patient Monitoring System does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate its safety and efficacy. The device does not introduce any new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 2 2011

MedApps, Inc.
c/o Mr. Kent Dicks
Founder / CEO
7975 North Hayden Road, Suite A-203
Scottsdale, AZ 85258

Re: K112559
Trade/Device Name: Modification to MedApps 2.0 – Remote Patient Monitoring System
Regulation Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: Class II (two)
Product Code: DRG
Dated: October 25, 2011
Received: November 3, 2011

Dear Mr. Dicks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**MedApps, Inc. (FDA-IU-8014 Rev C)** **EXHIBIT 01**
**STATEMENT OF INDICATIONS FOR USE**

510(k) Number: K112559

Preparation Date: August 31, 2011

Device Name: **Modification to MedApps 2.0 - Remote Patient Monitoring System**

Indications For Use:

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, a mobile over-the-counter wireless communication hub, or MedApps HealthAIR, a portable over-the-counter wireless communication hub, which connects to commercially available glucose meters, scales, blood pressure monitors and pulse oximeters and HealthCOM, MedApps' secure host server system.

MedApps Remote Patient Monitoring devices receive and store measurements collected from the described monitors, either wirelessly (HealthPAL) or tethered (HealthPAL or HealthAIR). MedApps devices do not alter the indicated use of the peripheral monitors that they integrate with. MedApps devices indicate successful or failed reception and transmission of data with visual and audio cues (HealthPAL via OLED display screen, verbal message and audio tones; HealthAIR via LED lights and audio tones). MedApps devices store collected data and transmit to HealthCOM using commercially available, FCC compliant, wireless telecommunication protocols (including but not limited to cellular GSM, CDMA and WiMax).

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use__X__
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112559